(19) Japanese Patent Office (11) Laid-Open No.

(12) JAPANESE UNEXAMINED PATENT GAZETTE (A) 3-66621

(51) Int. Cl.[5]	Code	P.O Ref. No.	(43) Laid-Open Date: 22 March 1991
A61K 33/10	ABY	7431-4C	
9/08	E	7624-4C	
33/14	ACV	7431-4C	
A61M 1/14	313	7720-4C	
	320	7720-4C	

Request for examination: not yet requested Number of claims 8 (Total 10 pages)

Title of the invention Process for preparing a dialysis solution, dialysis solution premix and a device for preparing a dialysis solution

(21) Application No. 1-204323

(22) Application Date 7 August 1989

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SPECIFICATION

1. Title of the invention

Process for preparing a dialysis solution, dialysis solution premix and device for preparing a dialysis solution

2. Claims

(1) A process for preparing a dialysis solution, characterized in that water is mixed with a dialysis solution premix which contains sodium bicarbonate, electrolyte and a liquid pH regulator and has a moisture content of 6 wt% or less.

(2) A dialysis solution premix described in Claim 1.

(3) A device for preparing a dialysis solution, characterized in that it is provided with a supply system having a dialysis solution premix supply means enclosing a set quantity of a

dialysis solution premix described in Claim 2 and a diluting water metering and supply means which supplies diluting water, and a mixing tank for holding the aforementioned dialysis solution premix supplied from the aforementioned dialysis solution premix supply means and the diluting water supplied from the aforementioned diluting water metering and supply means, and also a concentration determination means which determines the concentration of the dialysis solution prepared in the aforementioned mixing tank by a solution/mixing means which dissolves and mixes the aforementioned dialysis solution premix and aforementioned diluting water, and a discharge means which discharges a dialysis solution of the correct concentration determined by the aforementioned concentration determination means.

(4) A device for preparing a dialysis solution as described in Claim 3, in which the aforementioned dialysis solution premix supply means has a strip of packages comprising a plurality of fixed-dose containers in series, and an opening means which sequentially opens each of the fixed-dose containers comprising the strip of packages.

(5) A device for preparing a dialysis solution as described in Claim 3, in which the aforementioned dialysis solution premix supply means detachably houses a fixed-dose container enclosing a fixed quantity of dialysis solution premix and has an opening means which opens the aforementioned fixed capacity container.

(6) A device for preparing a dialysis solution as described in any of Claims 3 to 5, in which the aforementioned solution/mixing means comprises a circulation flow path connected with the aforementioned mixing tank and a contents circulation means which circulates the solution in the aforementioned mixing tank within the aforementioned circulation flow path, and an aforementioned dialysis solution premix supply means is connected to a constricted portion formed in the aforementioned circulation flow path.

(7) A device for preparing a dialysis solution as described in any of Claims 3 to 5, in which the aforementioned dialysis solution premix supply device has a dialysis solution premix grinding means and a filtering means.

(8) A device for preparing a dialysis solution as described in any of Claims 3 to 7 in which the aforementioned mixing tank is equipped with a rotating nozzle.

3. Detailed description of the invention

[Field of industrial application]

The present invention relates to a process for preparing a dialysis solution, dialysis solution premix and device for preparing a dialysis solution. More specifically, it relates to a process for preparing dialysis solutions which enables simplified preparation with fewer

preparation steps, dialysis solution premixes which simplify handling and transport and do not take up storage space, and devices for preparing a dialysis solution which make it easy to prepare dialysis solutions with the correct concentration.

[Prior art and problem which the invention is intended to solve]

In the prior art, dialysis solutions are prepared as follows.

A certain quantity of water is run into a dialysis solution preparation vessel, and then concentrated sodium bicarbonate solution (referred to hereafter as bicarbonate solution) and an electrolyte solution comprising electrolytes such as sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetate with the addition of a liquid pH regulator such as acetic acid or hydrochloric acid are put into the aforementioned dialysis solution preparation vessel and thoroughly mixed. The result is a prepared dialysis solution.

However, the aforementioned process for preparing a dialysis solution has the following problems.

It involves a large number of complex operations such as the operation of adding a bicarbonate solution to the water in the dialysis solution preparation vessel, the operation of adding an electrolyte solution, and the operation of thoroughly dissolving the bicarbonate solution and the electrolyte solution.

Since the bicarbonate solution and electrolyte solutions are both solutions, these take up considerable storage space before they are used to prepare a certain quantity of dialysis solution, and the fact that they are heavy means that they are difficult to transport. Considering the fact that dialysis solutions cannot be stored for long periods, and are prepared ready for use and in most cases dialysis solutions are prepared in hospitals by nurses and doctors, the difficulties of storing and transporting of the heavy bicarbonate solution and electrolyte solution pose a considerable hindrance to rapid and correct preparation of dialysis solutions.

The object of the present invention is to offer a process for preparing dialysis solutions, dialysis solution premixes and dialysis solution preparation devices which make it possible to prepare dialysis solutions easily by a simplified preparation procedure, without taking up storage space.

[Means for solving the problem]

The invention for solving the aforementioned problem as described in Claim 1 is a process for preparing a dialysis solution, characterized in that water is mixed with a dialysis solution premix containing sodium bicarbonate, electrolyte and a liquid pH regulator, with a moisture content of 6 wt% or less;

the invention as described in Claim 2 is a dialysis solution premix described in Claim 1;

the invention as described in Claim 3 is a device for preparing a dialysis solution, characterized in that it is provided with a supply system having a dialysis solution premix supply means enclosing a set quantity of a dialysis solution premix described in Claim 2 and a diluting water metering and supply means which supplies diluting water, and a mixing tank for holding the aforementioned dialysis solution premix supplied from the aforementioned dialysis solution premix supply means and the diluting water supplied from the aforementioned diluting water metering and supply means, and also a concentration determination means which determines the concentration of the dialysis solution prepared in the aforementioned mixing tank by a solution/mixing means which dissolves and mixes the aforementioned dialysis solution premix and aforementioned diluting water, and a discharge means which discharges a dialysis solution of the correct concentration determined by the aforementioned concentration determination means;

the invention as described in Claim 4 is a device for preparing a dialysis solution as described in Claim 3, in which the aforementioned dialysis solution premix supply means has a strip of packages comprising a plurality of fixed-dose containers in series, and an opening means which sequentially opens each of the fixed-dose containers comprising the strip of packages;

the invention as described in Claim 5 is a device for preparing a dialysis solution as described in Claim 3, in which the aforementioned dialysis solution premix detachably houses a fixed capacity container enclosing a fixed quantity of dialysis solution premix and has an opening means which opens the aforementioned fixed capacity container;

the invention as described in Claim 6 is a device for preparing a dialysis solution as described in any of Claims 3 to 5, in which the aforementioned solution/mixing means comprises a circulating flow path connected with the aforementioned mixing tank and a contents circulation means which circulates the solution in the aforementioned mixing tank within the aforementioned circulation flow path, and an aforementioned dialysis solution premix supply means is connected to a constricted portion formed in the aforementioned circulation flow path;

the invention as described in Claim 7 is a device for preparing a dialysis solution as described in any of Claims 3 to 5 in which the aforementioned dialysis solution premix supply device has a dialysis solution premix grinding means and a filtering means; and

the invention as described in Claim 8 is a device for preparing a dialysis solution as described in any of Claims 3 to 7 in which the aforementioned mixing tank is equipped with a rotating nozzle.

[Action]

In the invention as described in Claim 2, a moisture content of 6 wt% or less makes it possible to combine sodium bicarbonate, electrolytes and a liquid pH regulator, and possible to prepare a dialysis solution premix with sodium bicarbonate, electrolytes and a liquid pH regulator into a single premix; and in the invention described in Claim 1 a dialysis solution is prepared by dissolving this dialysis solution premix in water. To prepare this dialysis solution, all that is necessary is to add water to an aforementioned dialysis solution premix, so that dialysis solutions can be prepared by an exceedingly simple procedure. In addition, although the aforementioned dialysis solution premixes contains both sodium bicarbonate and an electrolyte, there is no precipitation of carbonate such as calcium carbonate because water is not present as a solvent; and although it contains both sodium bicarbonate and the liquid pH regulator glacial acetic acid, hardly any carbon dioxide is produced.

The aforementioned dialysis solution premix is not in the form of a solution, and therefore it does not occupy a large amount of storage space.

Employing a device for preparing a dialysis solution as described in Claim 3 to 8 with a dialysis solution premix which contains sodium bicarbonate, electrolyte and liquid pH regulator and has a moisture content of 6 wt% or less, enables automatic preparation of dialysis solutions with the correct concentration, without carbonate precipitation.

[Examples]

Preferred modes of this invention are described in detail below.

– <u>The dialysis solution premix</u> –

The dialysis solution premixes of this invention are solid compositions made by combining sodium bicarbonate, electrolyte and a liquid pH regulator into a single composition with a moisture content of 6 wt% or less. There are no particular restrictions as

to the form of the composition, other than being a solid form; examples include granules, tablet and powders.

There are no specific restrictions as to the sodium bicarbonate in the dialysis solution premixes of this invention, and this can be sodium bicarbonate used in prior processes for preparing dialysis solutions.

Similarly, the electrolyte used can be any electrolyte used in prior methods for preparing dialysis solutions, without any specific restrictions; examples include sodium chloride, potassium chloride, calcium chloride, magnesium chloride and sodium acetate. This electrolyte can be used in the form of crystals or in an anhydrous form; however, it is preferably anhydrous.

Similarly, glacial acetic acid or acetic anhydride, for example, can be used as the liquid pH regulator.

The content of sodium bicarbonate in a dialysis solution premix of the present invention is ordinarily 20-28 wt%, and more particularly 22-25 wt%; the content of electrolyte is 72-80 wt%, and more particularly 74-78 wt%, and the liquid pH regulator is ordinarily 0.2-0.5 wt% and more particularly 0.3-0.4 wt%.

Dialysis solution premixes of the present invention preferably contain substantially no water. Therefore, when storing a dialysis solution premix of this invention measures are needed in order to protect it from moisture, such as storage in a waterproof container. "Substantially" includes water contained in the form of water of crystallization. Dialysis solution premixes of this invention must be adjusted to a moisture content of 6 wt% or less. If the moisture content exceeds 6 wt%, carbonate will be produced in the dialysis solution premix by reaction between the sodium bicarbonate and the electrolyte, carbon dioxide will be produced by reaction between the sodium bicarbonate and acetic acid, and pH regulation becomes difficult.

Dialysis solution premixes of this invention can also contain glucose. In this case, the content of glucose will ordinarily be 5-20 wt% and more particularly 8-12 wt%, of the total.

– The process for preparing a dialysis solution –

The process for preparing a dialysis solution consists of mixing an aforementioned dialysis solution premix with water.

Specific examples of the process for preparing a dialysis solution are given below.

[Examples]

A dialysis solution premix with moisture 4.8 wt% was prepared as followed.

Sodium chloride 29.4 g, potassium chloride 0.94 g, calcium chloride dihydrate 1.31 g, magnesium chloride hexahydrate 0.77 g, sodium acetate trihydrate 4.16 g, sodium bicarbonate 12.8 g and glacial acetic acid 0.61 g were mixed in the form of a powder.

34.4 g of this dialysis solution premix was dissolved in water to prepare 3.5 l of dialysis solution.

– The device for preparing a dialysis solution –

The devices for preparing a dialysis solution indicated below can be used in the aforementioned process for preparing a dialysis solution.

As shown in Figure 1, device for preparing a dialysis solution 1 is provided with a dialysis solution premix supply means 3, which supplies a set quantity of dialysis solution premix to a mixing tank 2, and a diluting water metering and supply means 4, which supplies diluting water to the mixing tank 2, and a mixing tank 2, which mixes the aforementioned dialysis solution premix and diluting water, and a concentration determining means 6, which determines the concentration of the dialysis solution prepared in the aforementioned mixing tank 2 by a solution/mixing means 5 which dissolves and mixes the aforementioned dialysis solution premix and diluting water, and a discharge means 7, which discharges a dialysis solution with the correct concentration determined by this concentration determining means 6.

In the device for preparing a dialysis solution 1 illustrated in Figure 1, diluting water is supplied to a mixing tank 2 by the diluting water metering and supply means 4. Ordinarily, this diluting water is ideally warm water heated to a temperature of 20-35°C. Therefore, the diluting water metering and supply means 4[1] preferably has a heating means (not shown in the drawing). Moreover, a set quantity of dialysis solution premix is supplied to the mixing tank 2 from a dialysis solution premix supply means 3.

A dialysis solution premix described in Claim 2 can be ideally used as the dialysis solution premix supplied to the mixing tank 2 from the dialysis solution premix supply means 3; this premix can be any form, such as granules, tablets or a powder.

The aforementioned dialysis solution premix and aforementioned diluting water thus held in the mixing tank 2 are dissolved and mixed by means of a solution/mixing device 5.

The solution/mixing device 5 can be constituted by a contents circulating means such as a solution/mixing pump 5a and a circulation flow path 5b, for example, as shown in Figure 1.

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[1] The 5 in the Japanese is an evident error. Translator

The concentration of the dialysis solution dissolved and mixed by the dissolving and mixing means 5 and prepared in the mixing tank 2 is then determined by a concentration determination means 6, so that a dialysis solution with the correct concentration is discharged by the output means 7 to a storage tank 9 or a dialysis means (not shown in the drawings), for example. In the device shown in Figure 1, a water-discharge valve is used as the discharge means 7. In Figure 1, 50 is a drain.

The device for preparing a dialysis solution illustrated in Figure 1 can automatically prepare dialysis solutions with the correct concentration.

Various design modifications are possible in this device for preparing a dialysis solution 1, such as those indicated below.

For example, there are no specific restrictions as to the structure of the aforementioned dialysis solution premix supply means 3, provided that it supplies a set quantity of dialysis solution premix to the mixing tank 2; however, preferred forms for the dialysis solution premix supply means are cited below.

A structure provided with a strip of packets 12 comprising a series of fixed-dose containers 11 each enclosing a set quantity of a dialysis solution premix (see Figure 2) and an opening means such as a cutter (not shown in the drawing) which opens in sequence the fixed-dose containers 11 which make up the aforementioned strip of packages 12, and a conveying means such as a conveyor belt (not shown in the drawing) which conveys the aforementioned strip of package 12 to the aforementioned opening device, and an introduction means such as a conduit pipe (not shown in the drawing) which introduces the dialysis solution premix taken from the fixed-dose containers 11 opened by the aforementioned opening means into the aforementioned mixing tank 2.

A dialysis solution premix supply means with this sort of structure can supply the dialysis solution premix to the mixing tank 12 by a simple procedure such as sequentially opening a plurality of fixed-weight containers 11 which make up the aforementioned strip of packages by means of an opening means such as a cutter. And this dialysis solution premix supply means supplies the dialysis solution premix a little at a time and is convenient for preparing small quantities of dialysis solution.

The dialysis solution premix supply means can also have the following structure.

In Figure 3, the dialysis solution premix supply device 13 (termed the 2nd dialysis solution premix supply device, below) and a valve 14 are interposed in a pipe.

In this dialysis solution premix supply device 13 there is a detachably attached tubular fixed-dose container 16 (see Figure 14) filled with the dialysis solution premix and with thin

film 15 stretched over both ends; at the position where it is attached it faces a pipe 8d towards the valve 14, the end of which has an opening 18 which has sharp teeth 17, and at the position opposite this opening 18, it is faced by the end of a pipe 8b connecting with a concentration determination device 6 which constitutes a sharp cutter 19 and, as shown in Figure 4, has a backwards/forwards slideable opening 20. The aforementioned fixed-dose container 16 can be attached between the aforementioned opening 18 of the pipe 8d towards the valve 14 and the backwards/forwards slideable opening 20 of the pipe 8b connecting with the concentration determining device 6.

In this 2nd dialysis premix supply device 13, the aforementioned fixed-dose container 16 is incorporated by a conveying device not shown in the drawing, and the backwards/forwards slideable opening 20 is slid forward so that the thin film 15 of the aforementioned fixed-dose container 16 is broken; then the aforementioned slideable opening 20 is moved further forward and the other end of the aforementioned fixed-weight container 16 is pushed into the opening 18 of the pipe 8d towards the valve 14. The thin film stretched over the other end of the aforementioned fixed-dose container 16 is broken by the sharp teeth 17 on the opening 18 of the pipe 8d, and both ends of the aforementioned fixed-dose container 16 are fitted in an airtight manner to the openings 18 and 19 of the pipes 8d and 8b respectively, as in Figure 5.

Before the fixed-dose container 16 is attached to the openings 18 and 19 of the pipes 8d and 8b, the pipes 8b and 8d are closed by means of valves 10 and 14, so that there is no leakage of liquid from the mixing tank 2.

On fitting the fixed-weight container 16 to the pipes 8b and 8d, a solution/mixing pump 5a as mentioned previously is operated and the liquid in the mixing tank 2 flows in a circulation flow path 5b formed by pipes 8, 8a, 8b and 8d, and the dialysis solution premix inside the fixed-dose container 16 is washed into the mixing tank 2.

In this 2nd dialysis solution premix supply device 13, the dialysis solution premix inside the fixed-dose container 16 is washed out by the liquid in the mixing tank 2, and therefore the dialysis solution premix can be dissolved in the mixing tank 12 without any waste. Moreover, the fixed-dose container 16 is of the cartridge type and therefore is extremely simple to handle.

Furthermore, there is also the dialysis solution premix supply means shown in Figure 6, for example (referred to as the 3rd dialysis solution premix supply means below).

The 3rd dialysis solution premix supply means shown in Figure 6, like the 2nd dialysis solution premix supply means, has a pipe between the mixing tank 2 and the concentration determining means 6.

As Figure 6 shows, the inside diameter of the pipe 8e between the mixing tank 2 and concentration determination means 6 is constricted to give a narrow diameter and a fitting aperture 24 for a hopper 22 filled with the dialysis solution premix 60 opens into this narrow diameter region 21, so that when the hopper 22 is inserted into the fitting aperture 24 (in Figure 6, the direction of insertion is shown by an arrow), the hopper 22 opens into the inside of the pipe 8e. The hopper 22 also has an air vent 25.

In a 3rd dialysis premix supply means with a structure like that above, when liquid flows in the pipe 8e (the flow is shown by an arrow in Figure 6), the liquid flows faster in the narrow diameter region 21 than in the wider diameter region 23, and this fast flowing liquid produces a negative pressure, sucking the dialysis solution premix 60 in the hopper 22 into the pipe 8e.

This 3rd dialysis premix supply means has a simple structure because it does not need a special motor driven device for supplying dialysis solution premix 60 from the hopper 22 into the pipe 8e.

Another dialysis solution premix supply means (referred to below as the 4th dialysis solution premix supply device) has a structure with a dialysis solution premix supply component (not shown in the drawings), and a cylindrical solution tank 27 connected to the bottom thereof, which has many protrusions 26 and a filter means 40 such as a filter mesh inside and a pipe opening into the mixing tank 2, as shown in Figure 7 and Figure 8, and a pipe 28 extending from the pipe 8b shown in Fig. 3 and running around the inside surface of the aforementioned solution tank 27. The opening at the leading end of the aforementioned pipe 28 opens so as to form a vortex flow in the inside of the aforementioned solution tank 27.

In a 4th dialysis solution premix supply device with this sort of structure, the dialysis solution premix is first supplied to the aforementioned cylindrical solution tank 27 from a dialysis solution premix supply component not shown in the drawing. A vigorous vortex flow is formed in the cylindrical solution tank 27 by the discharge of water from the end of the pipe 28. The dialysis solution premix 60 in this cylindrical dissolution tank 27 is vigorously driven round on entering this vortex; the dialysis solution premix 60 which enters this vortex flow collides with the protrusions 26 formed on the inner surface and the vortex flow is made turbulent by the protrusions 26, producing a vigorous stirring action and as a result, the

dialysis solution premix is dissolved rapidly in the water even when it is in the form of granules, particles or tablets. The aqueous solution after dissolving the dialysis solution premix is filtered by the filter mesh, and then passes from the bottom of the solution tank 27 through a pipe into the mixing tank 2.

This 4th dialysis solution premix supply means is ideal for dissolving dialysis premixes in the form of granules, particles or tablets. In addition, the fact that water flow is used as the source of power for stirring means that the structure is simplified because there is no need for a motor such as a stirring motor.

In this device for preparing a dialysis solution 1, stirring in the mixing tank can be performed by means of a stirring device such as stirring vanes, however, if the rotating nozzles 29 shown in Figure 9 to Figure 11 is used, the liquid in the mixing tank can be stirred without the need for a drive motor to operate a stirrer.

These rotating nozzles 29 are placed in the mixing tank as shown in Figure 9.

In this the mixing tank 2, liquid is withdrawn from the mixing tank 2 and returned to the mixing tank 2 by a pipe 30 which has openings 31 around the end; the end of the pipe 30 is further covered by a rotatable enclosure 32, with a pair of spray tubes 33 extending in opposite directions from the periphery of this enclosure 32 as indicated in Figure 10, and the ends of these tubes have spray nozzles 34 which open in opposite directions, as shown in Figure 11.

In rotating nozzles 29 with this sort of structure, liquid is forced under pressure to the end of the pipe 30 by a solution/mixing pump 5 in the pipe 30, and emerges as a spray from the aforementioned openings 31 into the enclosure 32 and the liquid which sprays into the enclosure 32 is guided into the spray tubes 33 and sprays in opposite directions from the spray nozzles 34. As a result, the aforementioned pair of spray tubes 33 rotates under the action of the spray, and the sprayed liquid is dispersed spirally within the tank 2 by the rotation of the spray tubes. This brings about vigorous stirring in the mixing tank 2.

By using rotating nozzles 29 in this way, it is possible to stir the liquid in the mixing tank efficiently without a motor.

Above, we have described in detail examples of a dialysis solution preparation device of this invention; however, this invention is not restricted to the aforementioned examples, and other optional modifications to the design within the scope of the claims are possible.

For example, the concentration determination means can be placed within the mixing tank 2, and the mixing tank 2 can be a volumetric mixing tank provided with a volumetric

means such as a detector for the level of diluting water. Alternating operation with a plurality of mixing tanks as in Figure 12, for example, is also possible.

[Ben fits of the invention]

With this invention,

(1) it is possible to offer dialysis solution premixes which contain sodium bicarbonate with an electrolyte and a liquid pH regulator and have a moisture content of 6 wt% or less, in a single premix which does not take up storage space and is easy to handle and easy to transport;

(2) it is possible, by using the aforementioned dialysis solution premixes, to offer a process for preparing dialysis solutions which enables dialysis solutions to be prepared easily by dissolving this solid premix in water;

(3) it is also possible, by using a dialysis solution preparation device of the present invention, to prepare dialysis solutions automatically with the correct concentration.

4. Simplified description of the drawings

Figure 1 is a drawing explaining one example of a device of this invention for preparing a dialysis solution; Figure 2 is an explanatory drawing illustrating an example of a strip of packages fitted in the aforementioned device for preparing a dialysis solution; Figure 3 is an explanatory drawing illustrating another example of a device of this invention for preparing a dialysis solution; Figure 4 is an oblique drawing illustrating an example of the fixed-dose container in the dialysis solution premix supply means in the aforementioned device for preparing a dialysis solution; Figure 5 is a cross-sectional drawing illustrating the way in which the aforementioned volumetric container is attached to the pipe; Fig. 6 is a cross-sectional example illustrating another example of a dialysis solution premix supply means which can be incorporated in the aforementioned device for preparing a dialysis solution; Figure 7 and Figure 8 are explanatory drawing illustrating another dialysis solution premix supply means which can be incorporated in the aforementioned device for preparing a dialysis solution; Figure 9 is an explanatory drawing illustrating an example of rotating nozzles which can be incorporated in a device of this invention for preparing a dialysis solution; Figure 10 is a cross-sectional drawing of the aforementioned rotating nozzles, and Figure 11 is an oblique drawing illustrating the aforementioned rotating nozzles; Figure 12 is an explanatory drawing illustrating a further example of the present invention.

1 ... device for preparing a dialysis solution; 2 ... mixing tank; 3 ... dialysis solution premix supply means; 4 ... diluting water volumetric supply means; 5 ... solution/mixing means; 6 ... concentration determination means; 60 ... dialysis solution premix.

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